



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/910,354      | 07/20/2001  | Kevin A. Jarrell     | 2003320-0032        | 2372             |

7590                    08/25/2004

Brenda Herschbach Jarrell, Choates, Hall & Stewart  
Exchange Place  
53 State Street  
Boston, MA 02109

|          |
|----------|
| EXAMINER |
|----------|

VOGEL, NANCY S

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1636

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                   |                         |  |
|------------------------------|-----------------------------------|-------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>            | <b>Applicant(s)</b>     |  |
|                              | 09/910,354                        | JARRELL ET AL.          |  |
|                              | <b>Examiner</b><br>Nancy T. Vogel | <b>Art Unit</b><br>1636 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11 June 2004.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-5 and 11-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-5 and 11-14 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/24/04
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: Raw Sequence Listing Error Report.

## **DETAILED ACTION**

Claims 1-5, and 11-14 are pending in the case.

### ***Sequence compliance***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Raw Sequence Listing Error Report.

Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

### ***Information Disclosure Statement***

The information disclosure statement filed on 5/24/04 does not fully comply with the requirements of 37 CFR 1.98 because: there are no documents listed on the form. Since the submission appears to be *bona fide*, applicant is given **ONE (1) MONTH** from the date of this notice to supply the above mentioned omissions or corrections in the information disclosure statement. NO EXTENSION OF THIS TIME LIMIT MAY BE GRANTED UNDER EITHER 37 CFR 1.136(a) OR (b). Failure to timely comply with this notice will result in the above mentioned information disclosure statement being placed in the application file with the noncomplying information **not** being considered. See 37 CFR 1.97(i).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 5, 11, 12, 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Harney (US Patent 6,495,318) (newly cited).

Applicant's arguments regarding the rejection of claims 1, 2, 4, 5, and 11, set forth in the previous Office action mailed 11/20/03, have been considered but are moot in view of the new ground(s) of rejection.

This is a new grounds of rejection made necessary by applicant's amendments to the claims, submitted 6/11/04.

Harney disclose a method of preparing a vector, comprising providing at least two collections of nucleic acid molecules, wherein each of said collections comprises at least two isolated nucleic acids and wherein each of said isolated nucleic acids comprises a portion of vector sequence; selecting an individual nucleic acid molecule, or portion of a nucleic acid molecule from each of said collections; and admixing the selection nucleic molecules with one another under linkage conditions so that a hybrid molecule in which each of the selected nucleic

Art Unit: 1636

acid molecules or portions is linked together is produced (see Fig. 1 and column 1, lines 58- column 2, line 15). The reference discloses that the selected nucleic acid molecules contain at least one overhang that is complementary with an overhand on at least one of the other selected molecules (see column 2, lines 33-41). The reference discloses the further introduction of the hybrid molecule (i.e. vector) into a cell (see column 56, lines 18-23 for instance). The reference discloses that each nucleic molecule in each of said collections contains at least a portion of a vector element such as promoter, selectable marker, replication origin, transcription terminator, etc (Fig. 1 and column 7, lines 11-26). The reference discloses admixing under ligase conditions (see column 17, line 61-65).

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harney in view of Jarell (US Patent 5,498,531, "Jarrell '531") or Jarrell (US Patent 5,780,272 "Jarrell '272").

Applicant's arguments with respect to claims 1-5 and 11, set forth in the previous Office action mailed 11/20/03, have been considered but are moot in view of the new ground(s) of rejection.

This is a new grounds of rejection made necessary by applicant's amendments to the claims, submitted 6/11/04.

Harney is cited essentially for the reasons set forth above.

The difference between the references and the instant application is that the nucleic acid molecules each contain at least one intronic element that is characterized by an ability to trans-splice with a compatible intronic element on at least one of the other molecules.

However, by applicants' admission at page 23, lines 9-18 of the instant specification, Jarrell '531 and Jarrell '272 teach methods of preparing vectors comprising providing at least two nucleic acid molecules that contain intronic elements having an ability to trans-splice with each other.

It would have been obvious for one of ordinary skill in the art to have modified the method of preparing a vector, comprising providing at least two collections of nucleic acids wherein each of said collections comprises at least two isolated nucleic acids and wherein each of said isolated nucleic acids comprises a portion of vector sequence; selecting an individual nucleic acid molecule, or portion of a nucleic acid molecule from each of said collections; and admixing the selection nucleic molecules with one another under linkage conditions so that a hybrid molecule in which each of the selected nucleic acid molecules or portions is linked together is produced, as disclosed by Harney, by adding intronic elements to at least two of the nucleic acids, such that trans-splicing can take place between them, as taught by Jarrell '531 and Jarrell '272, in order to efficiently manipulate nucleic acids by specific cleavage and ligation (see column 2, line 33-column 3, line 40 of Jarrell '531, and col. 2, line 39 – col. 3, line 45 of Jarrell '272). One would have been motivated to do so in order to obtain the benefits of ease of manipulation of said nucleic acids, including joining said nucleic acids

Art Unit: 1636

and eliminating non-essential regions, as taught by Jarrell '531 and Jarrell '272.

Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is

Art Unit: 1636

(571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Terry a. McKelvey*  
TERRY MCKELVEY  
PRIMARY EXAMINER